Notice of Allowability	Application No. 10/656,769	Applicant(s) VARNUM ET AL.	
	Examiner Zachary Skelding	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10-9-07*.

2. ☒ The allowed claim(s) is/are *1,2,10,32-38,46,57-59 and 62-81*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *071224* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other *See Continuation Sheet*.

Continuation of Attachment(s) 9. Other: Email communication from Applicant requested by the Examiner, 12-21-07, 7 pages.

DETAILED ACTION

1. Applicant's amendment filed October 9, 2007 has been entered.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher Singer on December 22, 2007 and December 26, 2007.

IN THE CLAIMS

3. Claims 3-9, 39-45, 47-56, 60 and 61 have been canceled.

Claims 1, 2, 10-38, 46, 57-59 and 62-81 have been replaced with the following:

1. An isolated antibody or an antigen binding fragment thereof, that specifically binds human interleukin-1 receptor type 1 (IL-1R1), comprising a heavy chain and a light chain, wherein the heavy chain comprises a heavy chain variable region comprising SEQ ID NO: 16, or wherein said antigen binding fragment comprises an N-terminal or C-terminal deletion of SEQ ID NO: 16 and wherein said antigen binding fragment comprises at least SEQ ID NO: 63, SEQ ID NO:66, and SEQ ID NO: 69.

2. An isolated antibody or an antigen binding fragment thereof, that specifically binds human interleukin-1 receptor type 1 (IL-1R1), comprising a heavy chain and a light chain, wherein the light chain comprises a light chain variable region comprising SEQ ID NO: 18, or wherein said antigen binding fragment comprises an N-terminal or C-terminal deletion of SEQ ID NO: 18 and wherein said antigen binding fragment comprises at least SEQ ID NO: 71, SEQ ID NO: 73, and SEQ ID NO: 75.

10. An isolated antibody or an antigen binding fragment thereof, that specifically binds

human interleukin-1 receptor type 1 (IL-1R1), wherein the antibody comprises a heavy chain variable region comprising SEQ ID NO: 16, or the antigen binding fragment thereof, and a light chain variable region comprising SEQ ID NO: 18, or the antigen binding fragment thereof, wherein the antigen binding fragment of the heavy chain variable region comprises an N-terminal or C-terminal deletion of SEQ ID NO: 16 and wherein said antigen binding fragment of the heavy chain variable region comprises at least SEQ ID NO: 63, SEQ ID NO:66, and SEQ ID NO: 69 and the antigen binding fragment of the light chain variable region comprises an N-terminal or C-terminal deletion of SEQ ID NO: 18 and wherein said antigen binding fragment of the light chain variable region comprises at least SEQ ID NO: 71, SEQ ID NO: 73, and SEQ ID NO: 75.

32. The antigen binding fragment of claim 1, 2, or 10, wherein the heavy chain and light chain of the antigen binding fragment are connected by a flexible linker to form a single-chain antibody.

33. The antigen binding fragment of claim 32, which is a single-chain Fv antibody.

34. The antigen binding fragment of claim 1, 2, or 10, which is a Fab antibody fragment.

35. The antigen binding fragment of claim 1, 2, or 10, which is Fab' antibody fragment.

36. The antigen binding fragment of claim 1, 2, or 10, which is a $(Fab')_2$ antibody fragment.

37. The antibody or antigen binding fragment thereof, of claim 1, 2, or 10, which is a fully human antibody or antigen binding fragment.

38. The antibody or antigen binding fragment thereof, of claim 1, 2, or 10, wherein the antibody, or antigen binding fragment thereof, inhibits binding of IL-1 to human IL-1R1 receptor.

46. An isolated antibody comprising:

a. human heavy chain framework regions, a human heavy chain CDR1 region comprising SEQ ID NO: 63, a human heavy chain CDR2 region comprising SEQ ID NO: 66, and a human heavy chain CDR3 region comprising SEQ ID NO: 69; and

b. human light chain framework regions, a human light chain CDR1 region comprising SEQ ID NO: 71, a human light chain CDR2 region comprising SEQ ID NO: 73, and a human light chain CDR3 region comprising SEQ ID NO: 75.

57. The antibody or antigen binding fragment thereof of claim 10, which is an IgG2 antibody or antigen binding fragment.

58. The antibody or antigen binding fragment thereof of claim 10, which binds specifically to the amino acid sequence of SEQ ID NO: 76.

59. The antibody or antigen binding fragment thereof of claim 10, wherein the antibody or antigen binding fragment thereof binds specifically to a portion of the amino acid sequence of human IL-1R1, wherein the portion of the amino acid sequence to which the antibody specifically binds comprises the amino acid sequence YSV.

62. A composition comprising a pharmaceutically acceptable carrier, excipient or diluent, and the antibody or antigen binding fragment thereof of claim 10.

63. A pharmaceutical composition comprising a pharmaceutically acceptable carrier, excipient or diluent and a therapeutically effective amount of the antibody or antigen binding fragment thereof of claim 10.

64. An isolated antibody or an antigen binding fragment thereof that specifically binds

human interleukin-1 receptor type 1 (IL-1R1), comprising a heavy chain and a light chain, wherein the heavy chain comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 80, or wherein the antigen-binding fragment comprises an N-terminal or C-terminal deletion of SEQ ID NO: 80 and wherein said antigen binding fragment comprises at least SEQ ID NO: 63, SEQ ID NO: 66, and SEQ ID NO: 69.

65. An isolated antibody or antigen binding fragment thereof that specifically binds human interleukin-1 receptor type 1 (IL-1R1), comprising a heavy chain and a light chain, wherein the light chain comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO: 81, or wherein the antigen-binding fragment comprises an N-terminal or C-terminal deletion of SEQ ID NO: 81 and wherein said antigen binding fragment comprises at least SEQ ID NO: 71, SEQ ID NO: 73, and SEQ ID NO: 75.

66. An isolated antibody or antigen binding fragment thereof that specifically binds human interleukin-1 receptor type 1 (IL-1R1), wherein the antibody comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 80 or the antigen binding fragment thereof and a light chain variable region comprising the amino acid sequence of SEQ ID NO: 81 or the antigen binding fragment thereof, wherein the antigen-binding fragment of the heavy chain variable region comprises an N-terminal or C-terminal deletion of SEQ ID NO: 80 and wherein said antigen binding fragment comprises at least SEQ ID NO: 63, SEQ ID NO:66, and SEQ ID NO: 69, and the antigen binding fragment of the light chain variable region comprises an N-terminal or C-terminal deletion of SEQ ID NO: 81 and wherein said antigen binding fragment comprises at least SEQ ID NO: 71, SEQ ID NO: 73, and SEQ ID NO: 75.

67. An isolated antibody that specifically binds human interleukin-1 receptor type 1 (IL-1R1), comprising a heavy chain and a light chain, wherein the heavy chain comprises a heavy chain variable region comprising SEQ ID NO: 80.

68. An isolated antibody that specifically binds human interleukin-1 receptor type 1 (IL-1R1), comprising a heavy chain and a light chain, wherein the light chain comprises a light chain variable region comprising SEQ ID NO: 81.

69. An isolated antibody that specifically binds human interleukin-1 receptor type 1 (IL-1R1), wherein the antibody comprises a heavy chain variable region comprising SEQ ID NO: 80, and a light chain variable region comprising SEQ ID NO: 81.

70. The antigen binding fragment of any of claims 64, 65, or 66, wherein the heavy chain and light chain are connected by a flexible linker to form a single-chain antibody.

71. The antigen binding fragment of claim 70, which is a single-chain Fv antibody.

72. The antigen binding fragment of any of claims 64, 65, or 66 which is a Fab antibody fragment.

73. The antigen binding fragment of any of claims 64, 65, or 66 which is Fab' antibody fragment.

74. The antigen binding fragment of any of claims 64, 65, or 66 which is a $(Fab')_2$ antibody fragment.

75. The antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69 which is a fully human antibody or antigen binding fragment.

76. The antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69 wherein the antibody, or antigen binding fragment thereof, inhibits binding of IL-1 to human IL-1R1 receptor.

77. The antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69 which is an IgG2 antibody.

78. The antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69 which binds specifically to the amino acid sequence of SEQ ID NO: 76.

79. The antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69 wherein the antibody or antigen binding fragment thereof binds specifically to a portion of the amino acid sequence of human IL-1R1, wherein the portion of the amino acid sequence to which the antibody specifically binds comprises the amino acid sequence YSV.

80. A composition comprising a pharmaceutically acceptable carrier, excipient or diluent, and the antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69.

81. A pharmaceutical composition comprising a pharmaceutically acceptable carrier, excipient or diluent and a therapeutically effective amount of the antibody or antigen binding fragment thereof of any of claims 46, 64, 65, 66, 67, 68, or 69.

REASONS FOR ALLOWANCE

4. The following is an examiner's statement of reasons for allowance: In view of applicant's amendment to the claims filed October 9, 2007 and the applicant authorized examiner's amendment made herewith (see attached interview summary and e-mail message) the previous rejections of record are obviated and the claims are in condition for allowance.

   Claims 1, 2, 10, 32-38, 46, 57-59 and 62-81 are allowed.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
December 26, 2007

MICHAIL BELYAVSKYI, PH.D.
PRIMARY EXAMINER

12/26/07